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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,417	05/13/2005	Laurent Sandrin	P09275US00/DEJ	3075

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EXAMINER	
BOR, HELENE CATHERINE	
ART UNIT	**PAPER NUMBER**
3768	

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11/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,417	SANDRIN ET AL.	
	Examiner	Art Unit	
	Helene Bor	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Translation*.

DETAILED ACTION

The examiner recognizes the amendments made to the pending claims of 27 and 45 and the newly added claims 54-57. Thus under examination are the amended claims and newly added claims 27-57.

Response to Arguments

1. Applicant's corrections filed 09/04/2007 in regards to the drawings are accepted and all objections with regards to the drawings are withdrawn.

2. Applicant's corrections filed 09/04/2007 in regards to the specifications are accepted and all objections with regards to the specifications are withdrawn.

3. Applicant's arguments with respect to claim 27-57 have been considered but are moot in view of the new ground(s) of rejection necessitated by applicant's amendments.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 27-30 & 33-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Fink et al. (WO00/55616 previously cited by Applicant; reference is made to the English Translation by David Lawson a copy of which is attached hereto).

Claim 27: Fink teaches a device for measuring elasticity of a human or animal organ, or viscoelastic environments (Page 5, Line 34 – Page 6, Line 2) presenting an ultrasonic signal after ultrasonic illumination and consecutively establishing a representation in two or three dimensions of the elasticity (Page 10, Line 22-23 & Page 16, Line 16-22). Fink teaches at least one ultrasonic bar [linear strip] comprising a plurality of transducers (Page 10, Line 16 – 19), an excitor (Figure 1, Element 2) that generates and delivers a low-frequency, direct or indirect applied force (Page 8, Line 24-31), a receiver that acquires ultrasonic signals (Page 2, Line 24-28), a controller that commands and processes data (Figure 1, Element 4), and a scanner that carries out scanning with the bar in one dimension (1D) or in two dimensions (2D) in two perpendicular directions, respectively, to obtain a representation of the measure of the elasticity in two (2D) or three dimensions (3D) (Page 16, Line 16-22).

Claim 28: Fink teaches the device, wherein the excitor generates a mechanical vibration that can be transversal, longitudinal or a mixture of both (Page 10, Line 5-10).

Claim 29: Fink teaches the device, wherein the excitor (Figure 1, Element 2) generates a remote palpation using pressure of radiation (Page 9, Line 4-16) either with the transducer(s) used for acquiring ultrasonic signals or several transducers arranged around the viscoelastic environment (See arrangements in Figure 1 of Element 2 to Element 6 and arrangement of Figure 2 of Element 2 to Element 6).

Claim 30: Fink teaches the device, wherein the excitor (Figure 1, Element 2)

generates internal movements of the human or animal body (Page 9, Lines 4-6 & 14-16).

Claim 33: Fink teaches the device, wherein a space between the ultrasonic bar and the viscoelastic environment is constituted at least in part of water or any other element capable of assuring free passage of ultrasonic waves (Page 14, Line 8).

Claim 34: Fink teaches the device, wherein the mechanical vibration is obtained by one or several vibrating plates, piston(s) and/or bar(s) (Figure 1, Element 2).

Claim 35: Fink teaches "digitized in real time by a sampler" (Page 12, Page 1-7). It is inherent that digital-to-analog converters are needed to digitize the sampled signal. Fink teaches a loud speaker (Page 8, Line 24-31). It is inherent that the loudspeaker uses analog-to-digital converters to convert the electrical signal into sound, an analog signal. Fink teaches "linked to t[he] transducer". It is inherent that transmission lines are creating the link between elements.

Claim 36: Fink teaches the ultrasonic transmitters and receivers are arranged in proximity to the ultrasonic bar arranged as probe (Figure 2). Fink does not explicitly teach the components be in a proximity of less than 50 cm, however, Fink inherently teaches a device with component in such close proximity of less than 50 centimeters when the device is disclosed as a probe (Figure 2).

Claim 37: Fink inherently teaches the digital-to-analog (CNA) and analog-to-digital (CAN) converters as explained above in Claim 35. Fink teaches the components are arranged in proximity to the ultrasonic bar arranged in a housing

for hand-held operation (Col. 25, Line 29-39). Fink inherently teach the components be in a proximity of less than 50 cm as explained above in Claim 36.

Claim 38: Fink teaches a unit, constituted of the ultrasonic transducers and their on-board electronic components (Figure 1, Element 6, E, & M) are connected to the controller (Figure 1, Element S). Fink does teach the connections as to be capable of performance at real time speeds (Page 12, Line 1-11). It is inherent that Fink would have use a component part with very high-speed digital connections in order to perform in real time.

Claim 39: Fink teaches the device, comprising two ultrasonic bars [array] (Page 16, Line 1-8).

Claim 40: Fink teaches the device, comprising three ultrasound bars [array] (Page 16, Line 1-8) for measuring tissular speeds (Page 13, Line 8-10) along the directions y, x and z (Page 16, Line 1-8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 45-57 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (WO00/55616 English Translation by David Lawson) as applied to claim 27 above and in view of Dines et al. (US Patent No. 6,574,499).

Claim 45: Fink teaches a process for measuring elasticity of a human or animal organ, or viscoelastic environments (Page 5, Line 34 – Page 6, Line 2) presenting an ultrasonic signal after ultrasonic illumination and consecutively establishing a representation in two or three dimensions of the elasticity (Page 10, Line 22-23 & Page 16, Line 16-22) by using electronic scanning. Fink teaches generating a low-frequency applied force or signal (Page 8, Line 24-31) with an ultrasonic bar [linear strip] (Page 10, Line 16 – 19) and acquiring ultrasonic signals (Page 2, Line 24-28), generating ultrasonic images (Figure 1, Element 4a), calculating tissular speeds (Page 13, Line 8-10), and inverting [apodization] the data by recovering parameters describing the viscoelastic environment (Page 13, Line 11-13). Fink does not teach the displacement of a mechanical scanner. However, Dines teaches an ultrasound apparatus which utilizes a mechanical scanner for controlling and sensing the position of the ultrasound scanner (Col. 8, Line 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the non-mechanical scanning of Fink with an alternative equivalent expedient, the mechanical scanning, as taught by Dines (Page 15, Line 36 – Page 16, Line 8) to

implement the scanning, since it has generally been held to be within the skill level of the art to substitute alternative equivalent expedients.

Claim 46: Fink teaches the process, wherein the low-frequency applied force or signal has a frequency between 5 Hz and 1000 Hz (Page 8, Line 34-36).

Claim 47: Fink teaches the process, further comprising calculating tissular deformation speeds (Page 13, Line 8-10).

Claim 48: Fink teaches the process, further comprising measuring second derivatives of the longitudinal component of the deformation speed (Page 16, Equation I) along three orthogonal directions in space (Page 16, Line 16-22) during the calculation of the tissular speeds (Page 13, Line 8-10).

Claim 49: Fink teaches the process, wherein spatial derivatives of three components of the tissular speed along three directions in space are measured during calculation of the tissular speeds (Page 15, Line 36 – Page 16, Line 8).

Claim 50: Fink teaches the process, wherein acquiring the ultrasonic signals takes place while emitting an impulse with an ultrasonic transducer(s) that is reflected by particles contained in the viscoelastic environment (Page 6, Line 27 – 31).

Claim 51: Fink teaches the process, wherein acquiring ultrasonic signals is realized at a cadence of 1/T between 100 Hz and 100,000 Hz, where T is a period between two ultrasonic emissions (Page 12, Line 1-7).

Claim 52: Fink teaches the process, wherein acquiring ultrasonic signals is realized at a cadence of 1/T between 100 Hz and 100,000 Hz, where T is a period between two ultrasonic emissions (Page 12, Line 1-7).

Claim 53: Fink does not teach the displacement of a mechanical scanner. However, Dines teaches an ultrasound apparatus which utilizes a mechanical scanner for controlling and sensing the position of the ultrasound scanner (Col. 8, Line 9-12).

Claim 54: Fink teaches the device, wherein the excitor generates and delivers a low frequency, between 5 Hz and 1,000 Hz (Page 4, Line 36 – Page 5, Line 1), and scanning, with the bar [linear strip] (Page 10, Line 16 – 19) in one dimension or in two dimensions in order to focus three different points of elevation [multitude of points] (Page 2, Line 14-17), based on a direction perpendicular to the plane of the image (Page 16, Line 16-22). Fink does not teach the displacement of a mechanical scanner. However, Dines teaches an ultrasound apparatus which utilizes a mechanical scanner for controlling and sensing the position of the ultrasound scanner (Col. 8, Line 9-12).

Claim 55: Fink teaches wherein the scanning focuses three different points of elevation [multitude of points] (Page 2, Line 14-17) using a process selected from the group consisting of: a displacement of the echographic or ultrasonic bar, according to a direction perpendicular to the plane of the image, and an electronic modification of the laws of focalization of the echographic or ultrasonic bar (Page 10, Line 16-23 & Page 12, Line 24-28). Fink does not teach the displacement of a mechanical scanner. However, Dines teaches an ultrasound apparatus which utilizes a mechanical scanner for controlling and sensing the position of the ultrasound scanner (Col. 8, Line 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute

the non-mechanical scanning of Fink with a alternative equivalent expedient, the mechanical scanning, as taught by Dines (Page 15, Line 36 – Page 16, Line 8) to implement the scanning.

Claim 56: Fink teaches the process, wherein said generating a low frequency comprises generating a frequency between 5 Hz and 1,000 Hz (Page 4, Line 36 – Page 5, Line 1), and said method further comprises: acquiring ultrasonic signals in three different points of elevation [multitude of points] (Page 2, Line 14-17), based on the direction perpendicular to the plane of the image, to obtain a representation of the measure of the elasticity in two dimensions (2D) or three dimensions (3D) (Page 10, Line 22-23 & Page 16, Line 16-22).

Claim 57: Fink teaches the process, further comprising focusing the three different points of elevation [multitude of points] (Page 2, Line 14-17) using a process selected from the group consisting of: displacing the echographic or ultrasonic bar, according to a direction perpendicular to the plane of the image, displacing two echographic or ultrasonic bars, each displaced, and electronically modifying the laws of focalization of the echographic or ultrasonic bar. (Page 10, Line 16-23 & Page 12, Line 24-28). Fink does not teach the displacement of a mechanical scanner. However, Dines teaches an ultrasound apparatus which utilizes a mechanical scanner for controlling and sensing the position of the ultrasound scanner (Col. 8, Line 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the non-mechanical scanning of Fink with a alternative equivalent expedient, the

mechanical scanning, as taught by Dines (Page 15, Line 36 – Page 16, Line 8) to implement the scanning.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (WO00/55616 English Translation by David Lawson) as applied to claim 27 above, and further in view of Sarvazyan et al. (US Patent No. 5,810,731).

Claim 31: Fink teaches the device, wherein the excitor, either with the transducer(s) used for acquiring ultrasonic signals or one or several transducers arranged around the viscoelastic environment (See arrangements in Figure 1 of Element 2 to Element 6 and arrangement of Figure 2 of Element 2 to Element 6). Fink fails to teach the transducers being hyperthermal. Hyperthermal defined in reference to an elevation in temperature as explain by the applicant in Page 6 Paragraph [0014]. According to Steven L Jacques of the Oregon Graduate Institute of Science and Technology, he defines optoacoustic imaging as characterized by "a temperature rise" (Jacques, Steven L. and Guenther Paltauf. "Optoacoustic imaging: What is optoacoustic imaging?" Oct 2000. Oregon Medical Laser Center. 8 Feb. 2007. <http://omlc.ogi.edu/news/oct00/saratov2000/intro.html>.) Sarvazyan teaches the use of optoacoustic pulses in use for elasticity imaging (Col. 5, Line 43-47) for the generation of focused monopolar acoustic pulses (Col. 6, Line 24-27) to provide an increase in radiation force as compared with an ultrasonic pulse of the same energy (Col. 5, Line 54-57). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Fink by

including hyperthermal transducers as taught by Sarvazyan in order to provide an increase in radiation force as compared with an ultrasonic pulse of the same energy (Col. 5, Line 54-57).

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (WO00/55616 English Translation by David Lawson) as applied to claim 27 above and further in view of Varghese et al. (US Patent No. 7,166,075).

Claim 32: Fink teaches transducer that focuses at a plurality of different points of elevation and scanning is achieved by ultrasonic focalization (Page 12, Line 26-28). Fink fails to teach the ultrasonic bar is a 1.5 D bar. However, Verghese'075 teaches the 1.5 D transducers to have a transducer suitable for the image generating process (Col. 4, Line 38-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Fink by including the 1.5 D transducer of Varghese in order to have a transducer suitable for the image generating process (Col. 4, Line 38-39).

11. Claim 41 & 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (WO00/55616 English Translation by David Lawson) as applied to claim 39 and 27 above and further in view of Godik (US Patent No. 6,002,958).

Claim 41: Fink fails to teach the bars immersed in a hermetic container filled with a liquid. However, Godik teaches the bar immersed in a hermetic container filled with a liquid (Col. 7, Line 4-7) to have a low decay of ultrasound waves. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Fink by including the hermetic container as

taught by Godik in order have a low decay of ultrasound waves (Col. 7, Line 21-24).

Claim 43: Fink teaches the plurality of ultrasonic transducers (Figure 1, Element 6) but Fink does not teach the hermetic container comprises a plurality of orifices into which a mechanical vibrator and/or an ultrasonic transducer is/are introduced. However, Godik teaches an ultrasound transducer introduced into an orifice of a hermetic container or in other words "place at the cavity" (Col. 7, Line 6-7) for the objective of provoking local change in the tissue feature from point to point over the scanning direction and to compare the features of the nearby sites (Col. 4, Line 45-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Fink to include the hermetic container as taught by Godik for the objective of provoking local change in the tissue feature from point to point over the scanning direction and to compare the features of the nearby sites (Col. 4, Line 45-48).

Claim 44: Fink and Godik fail to specifically teach the orifices are situated at 90° (degrees) from each other or one from the other. However, Fink teaches using the ultrasound transducers laterally and axially (Page 16, Line 1-8). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the system of Fink in the container of Godik to satisfy the lateral and axial translation requirements of Fink which would result in the orifices having 90° greater angle between them.

12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (WO00/55616 English Translation by David Lawson) and in view of

Godik (US Patent No. 6,002,958) as applied to claim 41, 39 & 27 above, and further in view of Kruger (US Patent No. 6,490,470 B1).

Claim 42: Fink and Godik fail to teach a hermetic container connected to a rotator suitable for rotating the container. However, Kruger teaches a container connected to a rotator suitable for rotating the container (Col. 4, Line 33-38) in order to attain greater flexibility in positioning the radiation source and other elements of the device (Col. 3, Line 20-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Fink, and Godik by including the rotation connection as taught by Kruger in order to attain greater flexibility in positioning the radiation source and other elements of the device (Col. 3, Line 20-23).

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

ERIC F. WINAKUR
PRIMARY EXAMINER